PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference X15930	FOR FURTHER ACTION	See item 4 below	
International application No. PCT/US2004/000020	International filing date (day/month/year) 21 January 2004 (21.01.2004)	Priority date (day/month/year) 25 February 2003 (25.02.2003)]	
International Patent Classification (IPC) or national classification and IPC ⁷ A61K 31/4453, A61P 5/32, C07D 295/08			
Applicant ELI LILLY AND COMPANY			

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).				
2.	This REPORT consists of a total of 8 sheets, including this cover sheet.				
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.				
3.	3. This report contains indications relating to the following items:				
	Box No. I Basis of the report				
	Box No. II	Priority			
	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability			
	Box No. IV	Lack of unity of invention			
	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
	Box No. VI	Certain documents cited			
	Box No. VII	Certain defects in the intern	national application		
	Box No. VIII	Certain observations on the	e international application		
4.	4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).				
			Date of issuance of this report 26 August 2005 (26.08.2005)		
The International Bureau of WIPO			Authorized officer		
34, chemin des Colombettes 1211 Geneva 20, Switzerland			Simin Baharlou		
	Facsimile No. +41 22 740 14 35 Telephone No. +41 22 338 71 30				
Form PCT/IB/373 (January 2004)					

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To: See form PCT/SA/220 WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43b/s.1) Date of mailing (day/month/year) see form PCT/SA/210 (second sheet) Applicant's or agent's tile reference see form PCT/SA/220 International papilication No. PCT/SS/2004.000020 International papilication No. PCT/SS/2004.000020 International Patent Classification (IPC) or both national classification and IPC A61K31/4453, A61P5/32, COTD295/08 Applicant ELI LILLY AND COMPANY 1. This opinion contains indications relating to the following items: Sox No. I Basks of the opinion Box No. IV Incorporation of the international papilication of the pile of the	From	the	Dolling			REC'D Z 5 MAY 2004	
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2004/000020

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	RO	x No.	Basis of the opinion	
1.	Wit the	h rega langu	rd to the language , this opinion has been established on the basis of the international application in age in which it was field, unless otherwise indicated under this item.	
			opinion has been established on the basis of a translation from the original language into the following: lage , which is the language of a translation furnished for the purposes of international search er Rules 12.3 and 23.1(b)).	
2.	With	With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:		
	a. ty	ype of	material:	
	[⊐a	sequence listing	
	[∃ tal	ole(s) related to the sequence listing	
	b. format of material:			
		□ in	written format	
		□ in	computer readable form	
	c. tir	me of	illing/furnishing:	
		□ со	ntained in the international application as filed.	
	E	J file	d together with the international application in computer readable form.	
] fur	nished subsequently to this Authority for the purposes of search.	
3.		copies	lition, in the case that more than one version or copy of a sequence listing and/or table relating thereto een filed or furnished, the required statements that the information in the subsequent or additional is identical to that in the application as filed or does not go beyond the application as filed, as priate, were furnished.	
4.	Addi	tional	comments:	

PCT/US2004/000020 Box No. II **Priority** The following document has not been furnished: copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)). translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)). Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international

filing date indicated above is considered to be the relevant date. 3. Additional observations, if necessary:

WRITTEN OPINION OF THE

INTERNATIONAL SEARCHING AUTHORITY

International application No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2004/000020

Pov No III. Non catalytic and a second secon						
	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability					
The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:						
\boxtimes	claims Nos. 3,4					
because:						
⊠	the said international application, or the said claims Nos. 3,4 relate to the following subject matter which does not require an international preliminary examination (specify):					
	see separate sheet					
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):					
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.					
	no international search report has been established for the whole application or for said claims Nos.					
	the written form		has not been furnished			
			does not comply with the standard			
	the computer readable form		has not been furnished			
			does not comply with the standard			
	the tables related to the nucleot not comply with the technical re	ide a quire	and/or amino acid sequence listing, if in computer readable form only, do ements provided for in Annex C-bis of the Administrative Instructions.			
	See separate sheet for further of	letail	s			

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2004/000020

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1-5

No: Claims

Inventive step (IS)

Yes: Claims

1-5

No: Claims

Industrial applicability (IA)

Yes: Claims

1,2,5

No: Claims

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

 Certain published documents (Rules 43bis.1 and 70.10) and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

III. Non-establishment of opinion

Claims 3,4 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

V. Reasoned statement

Reference is made to the following document:

D1: EP-A-0 729 951

Novelty

The compound of claim 1 differs from the subject matter of D1 because of the SO_2CH_3 substituent - in D1 this position may be substituted by an $OSO_2(C_2-C_6)$ alkyl group.

Claims 1-5 fulfil the requirements of Article 33(2) PCT.

Inventive step

The compounds of D1 are described as being useful in the treatment of uterine fibrosis/endometriosis. The technical problem appears to be the provision of further agents with this activity. In the absence of a document showing that in similar compounds with the same activity an OSO₂alkyl and an SO₂alkyl group may be considered bioequivalent, there appears to be no incentive to modify the teaching of D1 by replacing the D1 OSO₂alkyl group by the present SO₂alkyl group. Thus claims 1-5 may be considered to be inventive.

Claims 1-5 fulfil the requirements of Article 33(3) PCT.

Industrial applicability

Claims 1, 2 and 5 fulfil the requirements of Article 33(4) PCT.

No unified criteria exist in the PCT Contracting States for assessing whether present claims 3 and 4 are industrially applicable. The patentability can be dependent upon the formulation of the claims. For example, the EPO does not consider claims to the use of a compound in medical treatment to be industrially applicable, but allows claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

PCT/US04/00020

VI. Certain documents cited

WO2004/009086, published on 29.1.04, with priority dates 22.7.02 and 25.2.03, discloses the hydrochloride salt of present claim 1 in example 4. If the first priority date of this document is validly claimed for this example, it would be relevant prior art for the assessment of novelty in the regional phase of examination.